ACC Health, Products & Science Policy (HPSP) Committee Dinner
June 27, 2017

Location: Art & Soul restaurant
415 New Jersey Avenue, NW
Washington, D.C.
6:00 p.m.

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Background:

- The ACC HPSP Committee consists of fairly senior company representatives. The Committee led ACC's advocacy on TSCA reform. Members include Connie Deford of Dow, who you know.
- Approximately 35 persons are expected to be in attendance: 30 company representatives and 5 ACC staff.
- Among the attendees are company representatives you spoke with or contacted regarding the Section 5 developments. Some of those representatives have returned your calls but have not caught up with you (e.g., Tom Grumbles at Sasol).

Suggestions for Remarks:

General Issues

- Members would be interested in any information on filling the OCSPP Assistant Administrator position, including timing.
- Committee members will be most interested in the outlook for EPA's work to implement the Lautenberg Chemical Safety Act. They are very familiar with the three framework rules, the scope of the evaluations on the first 10 chemicals, and the risk evaluation guidance.
- The Committee has an interest in ensuring appropriate resources are available to EPA to support LCSA implementation, and would be interested in hearing about plans for the fee rule and budget support for TSCA.
- The Committee is also aware that EPA has a relatively short period of time in which to have LCSA implementation recognized as meeting Congressional intent and delivering a more robust chemical regulatory system that protects health and the environment; fosters innovation, jobs, and competitive growth; and provides broad confidence that chemical risks are being addressed. The Committee would be particularly interested in understanding how the industry can best help EPA in LCSA implementation.

TSCA Section 5

- Committee members understand that EPA is working to eliminate the section 5 backlog. Eliminating the backlog is an important measure, but you should be aware that section 5 continues to be the industry's top concern.

- Many companies are concerned that the effort to eliminate the backlog is simply defaulting to regulation as the easiest administrative step. Many companies are still having problems moving submissions through the system; the review process is not actually moving faster. Indeed, many companies believe the section 5 program is defaulting to a hazard-based, rather than risk-based, review.
- It appears that about 90 percent of section 5 submissions are resulting in section 5(e) orders, a sharp departure from prior practice (which had 30-40 percent resulting in orders). Those orders take a long time to negotiate in back and forth with EPA (averaging 5-6 months just on the orders). The goal posts tend to move within that time frame.
- Program managers (the section 5 review coordinators) don't appear to have a consistent view on some elements. Some program managers still state that EPA will not issue non-section 5(e) orders/rules (despite having clear authority to do so), which conflicts with clear statements from OPPT management.
- We have several cases where the OPPT engineering reports have indicated no exposure potential exists, yet EPA still wants 90-day inhalation testing. In a case like that, there would be no risk.
- Companies are experiencing considerable difficulty in obtaining the engineering reports, and even understanding what analogue substance EPA is referring to and why (this means EPA uses analogue data but the submitter can't respond or provide a more appropriate analogue suggestion). Assumptions about exposures are often well beyond what would be expected based on the submitter's information; conditions of use are being assumed that have no basis. Requests for technical meetings are delayed or not addressed.
- The vast majority of section 5(e) consent orders are based on findings of insufficient information; in those cases EPA disregards the submitter agreement to require the use of personal protective equipment (PPE), even when data is provided to support the use.
- Several companies have been told that all new chemical reviews are approached from "an abundance of caution" that appears to translate into a more hazard-based approach.
- Members recognize that the Administrator has taken a personal interest in the section 5 program and that OPPT management is trying to address the problems. But many are concerned that the problems have not really been solved, and even if the backlog is reduced that the current approach will simply cause the backlog to recur.